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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,659	05/05/2005	Masahiro Nishimura	270257US0XPCT	1362

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EXAMINER	
KAROL, JODY LYNN	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/533,659	NISHIMURA ET AL.	
	Examiner	Art Unit	
	JODY L. KAROL	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/21/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendments and remarks filed on 12/21/2007. Claims 1 and 4 have been amended and new claims 5-18 have been added. Accordingly, claims 1-18 are pending and examined on the merits herein.

Information Disclosure Statement

1. The information disclosure statement (IDS) filed on 12/21/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

Status of Objections/Rejections

2. In view of Applicant's amendments to the specification, the objection to the specification in regards to the title, abstract, and trademarks are herein withdrawn.

3. The request for a substitute specification is withdrawn in view of Applicant's arguments.

4. The objection to claim 4 under 37 1.75(c) as being an improper multi-dependent claim is herein withdrawn in view of Applicant's amendment to claim 4.

5. Upon further consideration, the rejection of claims 1-3 on the ground of nonstatutory obviousness-type double patenting over claims 1-9 of U.S. Patent No. 5,618,799 in view of Fleischer et al. (WO 99/60998) are herein withdrawn.

6. In view of Applicant's amendment to claim 1, the rejection of claims 1-3 under 35 U.S.C. 102(b) as anticipated by Hara et al. (EP 1 224 937 A1) are herein withdrawn. However, Applicant's arguments that Hara et al. does not render obvious the claims have been fully considered, but were not found persuasive (see rejection below).

7. In view of the Applicant's arguments with respect to the rejection of claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (US 4,884,898) in view Ogawa et al. (6,130,329), the rejection is herein withdrawn.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied in the instant application. They newly applied rejections are necessitated by the amendment of claims 1 and 4, and the addition of new claims 5-18.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-18 rejected under 35 U.S.C. 103(a) as being unpatentable over Hara et al. (EP 1 224 937 A1).

The instant claims are directed to compositions for repairing injured skin comprising 50 to 90% by weight of saccharide, 0.5 to 10% by weight of povidone-iodine, 0.1 to 20% by weight of water, and 0.3 to 5% by weight of phospholipid.

Hara et al. teaches formulations for the treatment of bedsores, skin ulcers, or wounds, comprising 0.5 to 20% by weight of gelatin, 50 to 90%, preferably 60 to 80% by weight of sugar, and 0.5 to 10% by weight of an iodophor such as povidone-iodine, at a pH of 4-6 (see abstract and page 3, lines 38-39, and 45-50). In the examples, Hara et al. teaches water is present in 0-21% by weight (see page 5, Example 2, and page 6, Example 4). Hara et al. further teaches that additional components such as hydrogenated lecithin, a hydrogenated soybean phospholipid, may be present in up to 40% by weight (see page 3, line 55 to page 4, line 8).

In regards to the instant claims 2 and 7, Hara et al. teaches that sucrose, a soft white sugar, is preferable (see page 3, lines 42-44).

In regards to the instant claims 6, and 8-11, Hara et al. teaches in the examples compositions comprising the components within the claimed ranges. For instance, Example 2 comprises 70% by weight saccharide, 3% by weight povidone-iodine, and 1.5, 2.5, 3.5, 5, or 10% by weight water (see page 5, Example 2).

In regards to claims 13-16, Hara et al. teaches that the formulation can be combined with additional components such as base agents, thickeners, emulsifiers, stabilizers, and solvents that are used in pharmaceuticals. Among others, polyethylene glycol, alginic acid and salts thereof, polyoxyethylene alkyl ethers, polyoxyethylene hydrogenated castor oils, polyabsorbate, and sodium iodide are mentioned as the additional components (see page 3, lines 55 to page 4, line 7). Furthermore, gelatin, a thickener, is present in all of the compositions taught by Hara et al.

Hara et al. does not explicitly teach a composition where lecithin is present within the claimed range. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Hara et al. to formulate the claimed compositions with the lecithin and to optimize the amount of lecithin present. In this case, where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 UPSQ 90 (CCPA 1976). Furthermore, while the references do not explicitly teach the claimed range of lecithin, it is the Examiner's opinion that the determination of optimal or workable range of lecithin by routine experimentation is obvious absent showing of criticality of the claimed range. One having ordinary skill in the art would have been motivated to do this to obtain the desired emulsifying effects of lecithin.

Therefore, the invention as a whole would have been *prima facie* obvious to one skilled in the art at the time it was made.

Response to Arguments

10. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection. However, the arguments are addressed below to the extent that they are still applicable to the current rejections.

In response to Applicant's arguments that Hara et al. does not render obvious the claims, the Examiner notes that Applicant has not provided any evidence of the criticality of the herein claimed range of phospholipid. Applicant has merely compared a composition containing the phospholipid to a composition that does not contain a

phospholipid. Therefore, the comparison of the invention with the Comparative Product 1 on page 10 of the instant specification does not constitute a comparison with the closest prior art. However, Hara et al. clearly teaches that lecithin is an acceptable optional component and can be present at a concentration of up to 40% by weight. Therefore in view of the teachings of the cited prior art, the claims are properly rejected under 35 U.S.C. 103(a).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JODY L. KAROL whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617